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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,787	04/24/2001	Makoto Yamamori	85765-000200	7870

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EXAMINER

GRUNBERG, ANNE MARIE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/841,787

Applicant(s)
Makoto Yamamori

Examiner
Anne Marie Grunberg

Art Unit
1661



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-15 is/are pending in the application.
- 4a) Of the above, claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/24/01 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 6-10 without traverse in Paper No. 7 is acknowledged.

Applicant is reminded to cancel claims drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention employs wheat flour obtained from the endosperm of a wheat seed that lacks granule protein-1 (SGP-1) and has an apparent amylose content of about 35% or more.

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Since the wheat flour, and subsequently the wheat seed is essential to the claimed invention it must be both known and readily available to the public or can be made or isolated without undue experimentation. If the wheat seed is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of wheat seed that when planted will produce the plants from which the claimed flour may be obtained. Alternatively, the Applicant may satisfy the deposit requirement by depositing the parent cultivars which were used to obtain the hexaploid wheat that lacks starch granule protein-1. A deposit of 2500 seeds of each of the parent varieties or the wheat variety lacking the starch granule protein-1 is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific wheat seed has been deposited under the Budapest Treaty and that the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

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- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Additionally, applicant is advised that the specification must be amended to reflect the accession number for the deposit, the date of the deposit, a description of the deposited biological material, and the name and address of the depository in accordance with 37 CFR 1.809.

Written Description

Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims that recite wheat flour wherein the plant from which the seed is obtained and from which the flour is made is not specified and adequately described in the specification are rejected because the inventor was not in possession of the claimed

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invention at the time of filing. As such, all flour comprising starch which has an apparent amylose content of 35% or more is claimed, however all possible wheat seeds and moreover the plants that produce these seeds have not been adequately described in the specification. The specification only discloses progeny produced from crosses involving Chousen 30 or Chousen 57, Turkey 116, and Kanto 79.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. (It is not realistic to expect that the "complete structure" of a plant, or even a cell, could be described. Therefore the inquiry required by this portion of the written description guidelines is interpreted to be whether the phenotype of the plant has been described from which the flour is derived.) In this case, the few disclosed embodiments are not representative of the enormous number of products claimed. The claims encompass flour from every possible seed obtained from any wheat plant wherein the endosperm has been modified to lack SGP-1 and which has an apparent amylose content of at least 35%. Wheat plants from which seed used for flour is derived have many phenotype traits, which vary independently, so millions of possible phenotypes are possible and the flour from all of these are claimed. The specification discloses only flour made from the seed of progeny from crosses involving the parents Chousen 30 or Chousen 57, Turkey 116, and Kanto 79, but not the total population of flour obtained from endosperm of a wheat seed which is modified to lack SGP-1 and which has an apparent amylose content of at least 35% which is claimed. Next, then, it is determined whether a representative

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number of species have been sufficiently described by other relevant identifying characteristics. It is not possible to adequately describe the claimed products because there may be an infinite combination of parents that when crossed will provide progeny containing such an amylose content. Furthermore, there may already exist other wheat seeds that naturally contain such null alleles. One skilled in the art would not have been able to predict all of the resulting phenotypes of plants that could possibly produce such flour. The limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the huge genera recited in the claims at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genera. This rejection could be overcome by limiting the claims to flour derived from progeny of Chousen 30 or Chousen 57, Turkey 116, and Kanto 79 wheat described in the specification.

3. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to flour obtained from progeny of Chousen 30 or Chousen 57, Turkey 116, and Kanto 79, does not reasonably provide enablement for claims broadly drawn to flour obtained from any wheat plant that has seed with an apparent amylose content of at least 35%. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The specification only provides guidance for constructing a wheat plant having an amylose content of at least 35% made from crossing Chousen 30 or Chousen 57, Turkey 116, and Kanto 79. No guidance is provided regarding the construction of any other wheat plant having seed that has an apparent amylose content of 35% or more. In contrast, the claims are broadly drawn to all flour having an apparent amylose content of at least 35%.

Given the claim breadth, unpredictability as defined in MPEP 2164.03 and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to produce flour from any wheat seed other than the seed produced by crossing Chousen 30 or Chousen 57, Turkey 116, and Kanto 79.

Claims 6-10 are deemed free of the prior art, given the failure of the prior art to teach or suggest a wheat flour comprising wheat starch having an amylose content greater than 35%.

No claim is allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grünberg whose telephone number is (703) 305-0805. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (703) 308-4205. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anne Marie Grunberg
ANNE MARIE GRUNBERG
PATENT EXAMINER